



## Evaluation Report for Category B, Subcategory 2.6 Application

**Application Number:** 2014-1824  
**Application:** New / Changes EP or MA Product Chemistry-New combination of TGAIs  
**Product:** Luna sensation  
**Registration Number:** 32107  
**Active ingredients (a.i.):** Fluopyram, Trifloxystrobin  
**PMRA Document Number :** 2576136

### Purpose of Application

The purpose of this application was to register a new end-use product with a new combination of active ingredients, fluopyram and trifloxystrobin for the control of fungal diseases in leafy green and petiole vegetables, and brassica leafy vegetables.

### Chemistry Assessment

Luna Sensation is formulated as a suspension containing two active ingredients, fluopyram and trifloxystrobin both at a nominal concentration of 250 g/L. This end-use product has a density of 1.17 g/mL and pH of 6.8. The required chemistry data for Luna Sensation have been provided, reviewed and found to be acceptable.

### Health Assessments

Luna Sensation was of low acute oral, dermal and inhalation toxicity to rats. It was non-irritating to rabbit skin or eyes. The product was not a skin sensitizer in mice.

The use of Luna Sensation for use on leafy green vegetables and Brassica leafy vegetables is not expected to result in potential occupational or bystander exposure over the registered use of fluopyram or trifloxystrobin. No health risks of concern are expected from the new uses, provided that workers follow the label directions and wear the personal protective equipment identified on the label.

Residue data for fluopyram from field trials conducted in the United States, including Canadian representative growing regions, were submitted to support the domestic use of Luna Sensation on leafy vegetables and Brassica leafy vegetables. Fluopyram was applied to leaf lettuce, head lettuce, spinach, celery, cabbage, broccoli, cauliflower and mustard greens at label rates, and harvested according to label directions.

Residue data for trifloxystrobin from field trials conducted in the United States, including Canadian representative growing regions, were submitted to support the domestic use of Luna Sensation on leafy vegetables and Brassica leafy vegetables. Trifloxystrobin

was applied to leaf lettuce, head lettuce, spinach, celery, cabbage, broccoli, cauliflower and mustard greens at label rates, and harvested according to label directions, or at shorter preharvest intervals than proposed.

### Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for fluopyram was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover residues of fluopyram in/on crops and processed commodities are proposed as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the proposed MRLs for the raw agricultural commodities (RACs).

Commodity	Application Method/ Total Application Rate (g ai/ha)	PHI (days)	Fluopyram Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT			
Head lettuce	Foliar spray/ 494-513	0	0.583	5.286	Not required	None	<b>40</b> (CSG 4A: Leafy Greens)
Leaf lettuce	Foliar spray/ 495-506	0	1.239	9.048	Not required	None	
Spinach	Foliar spray/ 494-514	0	8.214	22.03	Not required	None	
Celery	Foliar spray/ 492-515	0	0.024	10.58	Not required	None	<b>20</b> (CSG 4B: Leaf Petioles)
Cabbage	Foliar spray/ 492-526	0	0.059	1.266	Not required	None	<b>4</b> (CSG 5A: Head and Stem <i>Brassica</i> )
Broccoli	Foliar spray/ 492-526	0	1.058	1.179	Not required	None	
Cauliflower	Foliar spray/ 492-526	0	0.02	0.835	Not required	None	
Mustard greens	Foliar spray/ 490-509	0	8.99	25.62	Not required	None	<b>50</b> (CSG 5B: Leafy <i>Brassica</i> Greens)

LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial

The recommendation for MRLs for trifloxystrobin was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover residues of trifloxystrobin and metabolite CGA-321113 in/on crops and processed commodities are proposed as shown in Table 2. Residues in processed commodities not listed in Table 2 are covered under the proposed MRLs for the raw agricultural commodities (RACs).

**TABLE 2. Summary of Field Trial and Processing Data Used to Support Maximum Residue Limits (MRLs) for Trifloxystrobin.**

Commodity	Application Method/ Total Application Rate (g ai/ha)	PHI (days)	Trifloxystrobin + CGA-321113 Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT			
Head lettuce	Foliar spray/ 278-291	0	<0.29	2.50	Not required	None	<b>30</b> (CSG 4A: Leafy Greens)
Leaf lettuce	Foliar spray/ 278-286	0	0.66	4.13	Not required	None	
Spinach	Foliar spray/ 279-289	0	4.82	10.41	Not required	None	
Celery	Foliar spray/ 276-289	0	<0.02	5.23	Not required	3.5 (CSG 4B)	<b>9</b> (CSG 4B: Leaf Petioles) <sup>1</sup>
Cabbage	Foliar spray/ 280-288	0	<0.04	0.60	Not required	None	<b>2</b> (CSG 5A: Head and Stem <i>Brassica</i> )
Broccoli	Foliar spray/ 276-290	0	0.46	0.70	Not required	None	
Cauliflower	Foliar spray/ 281-291	0	<0.02	0.36	Not required	None	
Mustard greens	Foliar spray/ 277-288	0	5.36	9.66	Not required	None	<b>30</b> (CSG 5B: Leafy <i>Brassica</i> Greens)

LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial

<sup>1</sup> The proposed MRL will replace the current MRL of 3.5 ppm in/on commodities of Crop Subgroup 4B.

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of fluopyram, and MRLs as proposed in Table 2 are recommended to cover residues of trifloxystrobin and metabolite CGA-321113. Residues in these crop commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

### Environmental Assessment

Luna Sensation contains the preservative 1,2-benzisothiazoline-3-one which contains low levels of dioxins and furans. These are being managed as outlined in the PMRA Regulatory Directive DIR99-03 for the implementation of TSMP. With the mitigation measures such as buffer zones and label statements, the use of Luna Sensation for the control of fungal diseases in leafy vegetables is not expected to pose environmental concerns.

### Value Assessment

A total of ten trials were submitted in support of the claims and to demonstrate the absence of phytotoxicity from the product. Of these, seven provided supportive efficacy data for the proposed Luna Sensation claims of efficacy. The other three trials did not show any disease pressure but were useful in demonstrating crop tolerance in representatives of the Brassica leafy vegetable group. All of the trials were conducted outside of Canada (USA, Spain, Philippines, and France). However, environmental data was provided to demonstrate the applicability of the results to Canadian conditions. Other active ingredients from the same and other mode of action groups are currently registered for these new fluopyram and trifloxystrobin uses. However, registration of Luna Sensation and its labeled claims will provide an additional product option with a convenient pre-mixed formulation of two effective fungicides to manage important diseases in the subject crop groups. The value of all claims was deemed to have been supported.

## Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and is able to support the registration of the new end-use product, Luna Sensation.

## References

PMRA Document Number	Reference
1669948	2008. Fluopyram+trifloxystrobin 500 SC fungicide (225 a.i./L fluopyram + 225 g a.i./L trifloxystrobin ) For control of Sclerotinia minor and Sclerotinia sclerotiorum in leafy green vegetables and leafy brassica vegetables. DACO: 10.2.3.3, 10.2.3.4, 10.3.2, 10.4, 10.5.1, 10.5.2, 10.5.4.
1669950	2008. Fluopyram + trifloxystrobin 500 SC fungicide (250 a.i./L fluopyram + 250 g a.i./L trifloxystrobin) for control of Septoria apiicola in leafy petiole vegetables. DACO: 10.2.3.3, 10.2.3.4, 10.3.2, 10.4, 10.5.1, 10.5.2, 10.5.4.
1669903	2008, Composition statement - Plant protection product - Fluopyram + trifloxystrobin SC 500 (250 + 250 g/L), DACO: 3.3.2,IIIA 1.4.1 CBI
1669905	2008, Product chemistry of fluopyram + trifloxystrobin 500 SC, DACO: 3.3.1,3.3.2,IIIA 1.4.2 CBI
1669907	2008, Product chemistry of fluopyram + trifloxystrobin 500 SC, DACO: 3.2.2,IIIA 1.4.5.1 CBI
1669909	2008, Discussion of the formation of impurities of fluopyram & trifloxystrobin - SC 500 (250+ 250 g/L), DACO: 3.2.3,IIIA 1.4.5.2 CBI

1669935	2008, Physical, chemical and technical properties of fluopyram + trifloxystrobin SC 500 (250+250) G, DACO: 3.5.1,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9,3.7,8.2.2.1,8.2.3.6,IIIA 2.1,IIIA 2.4.2,IIIA 2.5.1,IIIA 2.5.2,IIIA 2.5.3,IIIA 2.6.1,IIIA 2.8.2,IIIA 2.8.3.1,IIIA 2.8.3.2,IIIA 2.8.5.2,IIIA 2.8.6.1,IIIA 2.8.8.2
1669937	2008, Miscibility of fluopyram & trifloxystrobin - SC 500 (250+ 250 g/L), DACO: 3.5.13,IIIA 2.11
1669938	2008, Dielectric breakdown voltage of fluopyram & trifloxystrobin - SC 500 (250+ 250 g/L), DACO: 3.5.15,IIIA 2.12
1669940	2008, Storage stability of fluopyram + trifloxystrobin SC 500 (250+250) G - [Packaging material: HDPE] - Interim report, DACO: 3.5.10,3.5.14,IIIA 2.13,IIIA 2.7.1,IIIA 2.7.3,IIIA 2.7.4,IIIA 2.7.5
1669941	2008, Container material of fluopyram & trifloxystrobin - SC 500 (250+ 250 g/L), DACO: 3.5.5,IIIA 2.14
1669942	2008, Safety relevant technical properties of fluopyram + trifloxystrobin SC 500 (250 + 250) g/L - Final report -, DACO: 3.5.11,3.5.12,3.5.8,IIIA 2.2.1,IIIA 2.2.2,IIIA 2.3.1,IIIA 2.3.3
1669943	2008, Statement regarding the density for the study Physical, chemical and technical properties of fluopyram + trifloxystrobin SC 500 (250+250) G DART number: M-291446-01-1, DACO: 3.5.6,IIIA 2.6.1
1669946	2008, Validation of GLC-method AM009707MF1 - Determination of fluopyram and trifloxystrobin in formulations -, DACO: 3.4.1,IIIA 5.2.1,IIIA 5.2.2
1669947	2008, Determination of fluopyram and trifloxystrobin in formulations - Assay – [CBI removed], DACO: 3.4.1,IIIA 5.2.1,IIIA 5.2.2
2535733	2009, Storage Stability Data of fluopyram + trifloxystrobin SC 500 (250+250 g/L), DACO: 3.5.10,3.5.14,IIIA 2.13,IIIA 2.7.1,IIIA 2.7.2,IIIA 2.7.3,IIIA 2.7.4,IIIA 2.7.5 CBI
2535734	2015, Validation of [CBI removed]-method AM009707MF1 - Determination of fluopyram and trifloxystrobin in formulations - fluopyram + trifloxystrobin SC 500 (250+250 g/L), DACO: 3.4.1,IIIA 5.2.1 CBI
1669960	2008, AE C656948 500 SC and trifloxystrobin 500 SC - Magnitude of the residue in/on leafy vegetables (crop subgroup 4), DACO: 7.4.1,7.4.2,7.4.6,IIIA 8.3.2
1669962	2008, AE C656948 500 SC and trifloxystrobin 500 SC - Magnitude of the residue in/on head and stem brassica (crop subgroup 5A), DACO: 7.4.1,7.4.2,7.4.6,IIIA 8.3.3

1669963	2008, AE C656948 500 SC + trifloxystrobin 500 SC - Magnitude of the residue in/on leafy brassica greens (crop subgroup 5B), DACO: 7.7,IIIA 8.3.4
1669952	2008, AE C656948 & trifloxystrobin SC 250 & 250 - Acute toxicity in the rat after oral administration, DACO: 4.6.1,IIIA 7.1.1
1669953	2008, AE C656948 & trifloxystrobin SC 250 & 250 - Acute toxicity in the rat after dermal application, DACO: 4.6.2,IIIA 7.1.2
1669954	2008, AE C656948 & trifloxystrobin SC 250 & 250 - Activity ID TXGMP033- Acute inhalation toxicity in rats, DACO: 4.6.3,IIIA 7.1.3
1669955	2008, AE C656948 & trifloxystrobin SC 250 & 250 - Acute skin irritation/corrosion on rabbits, DACO: 4.6.5,IIIA 7.1.4
1669956	2008, AE C656948 & trifloxystrobin SC 250 & 250 (AE C656948 + TFS SC 250+250 G) - Acute eye irritation on rabbits, DACO: 4.6.4,IIIA 7.1.5
1669957	2008, AE C656948 and trifloxystrobin SC 250 & 250 - Evaluation of potential dermal sensitization in the local lymph node assay in the mouse, DACO: 4.6.6,IIIA 7.1.6
1599582	2008, AE C656948 500 SC - Magnitude of the residue in/on fruiting vegetables (crop group 8 ), DACO: 7.2.1,7.2.4,7.4.1,7.4.2,7.4.6,IIA 4.3,IIA 6.3.3
1599583	2008, AE C656948 500 SC - Magnitude of the residue in/on tomato processed commodities, DACO: 7.4.5,IIA 6.5.3
1599672	2008, Determination of the residues of AE C656948 in/on tomato fruit and the processed fractions (raw juice; washings; fruit, washed; juice; peel; ...) after spraying of AE C656948 (500 SC) in the field in Portugal, Italy and Southern France, DACO: 7.4.5,IIA 6.5.3
1599673	2008, Determination of the residues of AE C656948 in/on tomato fruit and the processed fractions (raw juice; washings; fruit, washed; juice; peel; preserve; fruit, peeled; peeling water; puree; raw puree; strain rest) after spraying of AE C656948 (500 SC) in the field in Italy, DACO: 7.4.5,IIA 6.5.3
1654362	2008, AE C656948 500 SC - Magnitude of the residue in/on root vegetables except sugar beet (crop subgroup 1B), DACO: IIA 6.3.6,IIA 6.3.7
1661265	2008, AE C656948 500 SC - Magnitude of the residue in/on root vegetables except sugar beet (crop subgroup 1B), DACO: IIA 6.3.6,IIA 6.3.7
1654377	2008, AE C656948 500 SC - Magnitude of the residue in/on orange processed commodities, DACO: 7.4.5,IIA 6.5.3
1661284	2008, AE C656948 500 SC - Magnitude of the residue in/on orange processed commodities, DACO: 7.4.5,IIA 6.5.3
1654381	2008, AE C656948 500 SC - Magnitude of the residue on sunflower processed commodities, DACO: 7.4.5,IIA 6.5.3

1661289	2008, AE C656948 500 SC - Magnitude of the residue on sunflower processed commodities, DACO: 7.4.5,IIA 6.5.3
1654382	2008, AE C656948 500 SC - Magnitude of the residue on plum processed commodities, DACO: 7.4.5,IIA 6.5.3
1661290	2008, AE C656948 500 SC - Magnitude of the residue on plum processed commodities, DACO: 7.4.5,IIA 6.5.3
1654389	2008, Determination of the residues of AE C656948 and tebuconazole in/on round cabbage head and the processed fractions (washings; cooking water; head, cooked; head, washed) after spraying of AE C656948 & HWG 1608 (400 SC) in the field in Souther, DACO: 7.4.5,IIA 6.5.3
1661292	2008, Determination of the residues of AE C656948 and tebuconazole in/on round cabbage head and the processed fractions (washings; cooking water; head, cooked; head, washed) after spraying of AE C656948 & HWG 1608 (400 SC) in the field in Souther, DACO: 7.4.5,IIA 6.5.3
1654397	2007, Determination of the residues of AE C656948 and tebuconazole in/on round cabbage head and the processed fractions (washings; cooking water; head, cooked; head, washed) after spraying of AE C656948 & HWG 1608 (400 SC) in the field in Norther, DACO: 7.4.5,IIA 6.5.3
1661297	2007, Determination of the residues of AE C656948 and tebuconazole in/on round cabbage head and the processed fractions (washings; cooking water; head, cooked; head, washed) after spraying of AE C656948 & HWG 1608 (400 SC) in the field in Norther, DACO: 7.4.5,IIA 6.5.3
1661147	2008, AE C656948 500 SC + trifloxystrobin 500 SC - Magnitude of the residue in/on globe artichoke, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661154	2008, AE C656948 500 SC - Magnitude of the residue in/on dry bulb onions, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661159	2008, AE C656948 500 SC - Magnitude of the residue in/on green onions, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661174	2008, AE C656948 500 SC and trifloxystrobin 500 SC - Magnitude of the residue in/on leafy vegetables (crop subgroup 4), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1669960	2008, AE C656948 500 SC and trifloxystrobin 500 SC - Magnitude of the residue in/on leafy vegetables (crop subgroup 4), DACO: 7.4.1,7.4.2,7.4.6,IIA 8.3.2
1983751	2010, AE C656948 500 SC and trifloxystrobin 500 SC - Magnitude of the residue in/on leafy vegetables (crop subgroup 4), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661180	2008, AE C656948 500 SC and trifloxystrobin 500 SC - Magnitude of the residue in/on head and stem brassica (crop subgroup 5A), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1

1669962	2008, AE C656948 500 SC and trifloxystrobin 500 SC - Magnitude of the residue in/on head and stem brassica (crop subgroup 5A), DACO: 7.4.1,7.4.2,7.4.6,IIA 8.3.3
1661199	2008, AE C656948 500 SC - Magnitude of the residue in/on leafy brassica greens (crop subgroup 5B), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1669963	2008, AE C656948 500 SC + trifloxystrobin 500 SC - Magnitude of the residue in/on leafy brassica greens (crop subgroup 5B), DACO: 7.7,IIA 8.3.4
1661209	2008, AE C656948 500 SC - Magnitude of the residue in/on succulent shelled pea and bean (crop subgroup 6B), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661210	2008, AE C656948 500 SC - Magnitude of the residue in/on edible-podded legume vegetables (crop subgroup 6A ), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661221	2008, AE C656948 500 SC - Magnitude of the residue on citrus (crop group 10), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661236	2008, AE C656948 500 SC + pyrimethanil 600 SC - Magnitude of the residue in/on caneberry, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661237	2008, AE C656948 500 SC + pyrimethanil 600 SC - Magnitude of the residue in/on bushberry (crop subgroup 13B), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661249	2008, AE C656948 500 SC - Magnitude of the residue in/on grass forage, fodder, and hay (crop group 17) and grass for seed, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661250	2008, AE C656948 500 SC + trifloxystrobin 500 SC - Magnitude of the residue in/on globe herbs (crop subgroup 19A), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661251	2008, AE C656948 500 SC + trifloxystrobin 500 SC - Magnitude of the residue in/on spices, except black pepper (crop subgroup 19B), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661252	2008, AE C656948 500 SC - Magnitude of the residue in/on peanuts, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661258	2008, AE C656948 500 SC: Magnitude of the residue on hops, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661259	2008, AE C656948 500 SC - Magnitude of the residue in/on sunflower, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2427018	2013, Fluopyram 500 SC and fluopyram 400 SC - Magnitude of the residue in/on potato, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2427239	2013, Fluopyram 500 SC and fluopyram 400 SC - Magnitude of the residue in/on potato, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2427021	2013, Fluopyram 500 SC and fluopyram 400 SC - Magnitude of the residue in cotton (Amended) - (i-MRL), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.2



2427022	2014, Fluopyram 500 SC and fluopyram 400 SC - Magnitude of the residue in/on citrus - Fluopyram 500 SC (short code - 129306) - Fluopyram 400 SC (short code - 151196) (i-MRL), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.2
2427023	2013, Fluopyram 500 SC and Fluopyram 400 SC - Magnitude of the residue in/on peanut (i-MRL), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.2
2427035	2012, BYI 02960, fenamidone, fluopyram, and spiromesifen - Magnitude of the residue in sugarcane processed commodities in Florida (rotational crop regional tolerance) - (Amended) (i-MRL), DACO: 7.4.5,IIA 6.5.3
2427043	2013, Fluopyram 500 SC and fluopyram 400 SC - Magnitude of the residue in/on cotton processed commodities (i-MRL), DACO: 7.4.5,IIA 6.5.3
2427044	2012, BYI 02960, fenamidone, fluopyram, and spiromesifen - Magnitude of the residue in sugarcane in Florida (rotational crop regional tolerance) (Amended) (i-MRL), DACO: 7.4.4,IIA 6.6.3
2535486	2015, Fluopyram- Proposal to Modify Petition for tolerances-version#4 (final), DACO: 7.1,7.8,IIA 6.7.2
2572513	2015, Waiver request: AE C656948 500 SC - Magnitude of the residue in/on barley (as part of crop groups 15 and 16, except rice): Bayer CropScience response to the PMRA deficiency note for fluopyram on barley, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2572514	2015, Waiver request: AE C656948 500 SC - Magnitude of the residue in/on canola (crop group 20A): Bayer CropScience response to the PMRA deficiency note for fluopyram on canola, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2572515	2015, Waiver Request: AE C656948 500 SC - Magnitude of the residue in/on wheat (as part of crop groups 15 and 16, except rice): Bayer CropScience response to the PMRA deficiency note for fluopyram on wheat, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2572518	2015, Waiver request: AE C656948 500 SC - Magnitude of the residue in/on small-sized tomatoes (as part of crop groups 8-09A): Bayer CropScience response to the PMRA deficiency note for fluopyram on tomatoes, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2577848	2015, Fluopyram - Projected Percent Crop Treated - Canada, DACO: 7.1,7.8,IIA 6.7.2

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